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FOOD SAFETY AND QUALITY

FDA Can Improve Monitoring of Imported Cheese

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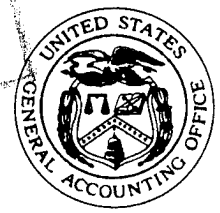

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the Food and Drug Administration's (FDA) efforts to ensure the safety of imported cheese. Our testimony today is based on our July 6, 1992, report responding to Mr. Roth's request that we assess FDA's ability to protect American consumers from unsafe imported cheese.

In summary, FDA is responsible for ensuring that foreign cheese imported into the United States meets the same safety and labeling standards applied to domestic cheese. Some exporting countries do not have food safety standards similar to those in the United States, and their cheeses have had a higher incidence of contamination than cheese products imported from other countries. Although FDA has tried to develop certification programs that require foreign governments to ensure that their countries' exported products meet U.S. standards, it has only one foreign certification program for cheese--with France. However, FDA has not formally monitored the French program and does not have sufficient data to determine whether the program has been effective.

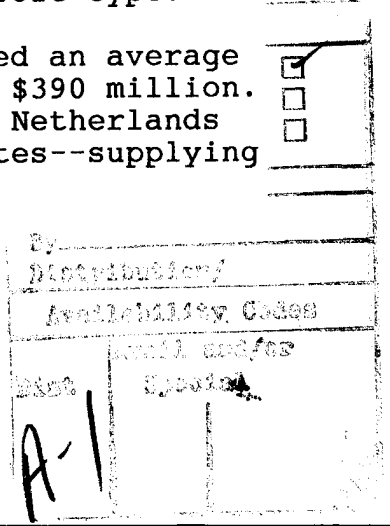
Because FDA regulates imported cheese just like any other imported food under its jurisdiction, many of the concerns that we have reported on in the past about FDA's import program are also relevant to imported cheese. Among these concerns is the low percentage of product samples that FDA collects and analyzes for contamination.

Before I discuss more detailed findings, let me briefly give you some background on the risks associated with cheese and how FDA regulates imported cheese.

BACKGROUND

FDA categorizes cheese as a high-risk food because it is susceptible to potentially fatal contamination from bacteria such as Listeria monocytogenes and salmonella. Soft, semi-soft, and surface-ripened cheese (such as Brie and Camembert) or other types of cheese made from unpasteurized milk are more susceptible to microbial contamination, because of their high moisture content and potentially high levels of bacteria, than are hard cheeses or cheeses made from pasteurized milk. About 35 percent of all cheese imported to the United States is of the soft or semi-soft type.

Since 1985 the United States has annually imported an average of about 290 million pounds of cheese valued at about $390 million. Italy, France, Denmark, New Zealand, Finland, and the Netherlands are the largest exporters of cheese to the United States--supplying about 60 percent of the nation's imported cheese.



While FDA inspects domestic cheese-processing facilities, it does not have authority over foreign cheese-processing facilities and cannot inspect them to determine whether they are using good manufacturing practices to produce pure and safe products. Instead, FDA relies primarily on testing and inspecting imported cheese shipments when they are offered for entry into the United States. Most imported cheese shipments--about 75 percent--enter the United States through FDA's New York district.

Initially, FDA's district inspectors conduct a limited paperwork review of all imported cheese entries. This review helps FDA determine whether to release an entry or examine it further. Further examinations may consist of a more detailed paperwork examination; or a quick, visual examination of the product; or a sample collection and laboratory analysis of the product. FDA detains products that appear to be in violation of U.S. standards, and these products must be exported, destroyed, or reconditioned to bring them into compliance with U.S. laws and regulations.

According to FDA officials, inspections and sampling decisions are generally targeted to those cheese products or importers that have a history of violations. Problem commodities and importers that should be inspected are identified through import alerts issued to all FDA districts. Imported cheese products or importers that consistently violate U.S. standards may also be placed on automatic detention, which allows districts to detain the product without sampling or analysis. Through automatic detention, FDA shifts the burden of proving that a product is safe to the importer, who must provide FDA with an acceptable laboratory analysis certifying that the product overcomes the appearance of a violation before it is released for distribution in the United States.

FDA'S EFFORTS TO REGULATE IMPORTED CHEESE

According to FDA officials, the agency increased efforts to regulate the safety of domestic and imported cheese in 1985, after a domestic, Mexican-style soft cheese contaminated with listeria was implicated in 84 deaths and 150 illnesses in California. After the 1985 listeria outbreak, FDA conducted extensive testing of both domestic and imported soft cheeses. FDA collected samples of imported soft cheese from 15 countries and found listeria contamination and indications of inadequate pasteurization in some cheese, especially cheese from France, Italy, and the Federal Republic of Germany. As a result, in 1986 FDA placed all imported soft cheeses on import alert status and a number of soft cheeses from France on automatic detention.

In response to FDA's actions, the French and Italian governments proposed certification programs for testing cheese exported to the United States to ensure that it meets U.S.

standards. However, FDA and the Italian government were unable to reach agreement on a number of issues, and only the French certification program was actually implemented.

Under the French certification program for soft cheese, which became effective February 1987, the French government agreed to (1) inspect soft-cheese manufacturing plants exporting to the United States and to certify that they are listeria-free, (2) regularly provide FDA with a current list of all plants certified under the program, and (3) issue a health certificate to certified plants that must accompany all shipments of cheese to the United States. FDA does not accept health certificates that are more than 6 months old or that do not state the minimum time and temperature schedule the plant uses to pasteurize milk.

THE EFFECTIVENESS OF THE FRENCH CERTIFICATION PROGRAM IS UNKNOWN

Although FDA officials believe that the French certification program is working very well and has reduced the incidence of listeria in French cheese, FDA has not formally monitored the program and has insufficient data to support this belief. For example, FDA's data base did not distinguish between samples collected for auditing the certification program and other French cheese samples until 1991. Thus, FDA had no way of knowing which samples of French cheese represented cheese imported under the certification program. Further, although FDA began identifying samples taken from certified cheese in 1991, the reliability of the data FDA has collected is questionable because it is unclear how many samples were actually collected because of inconsistencies in FDA's data bases. Three FDA data bases had three different totals for the number of French soft-cheese audit samples collected in fiscal year 1991.

CONCERNS ABOUT OTHER ASPECTS OF FDA'S IMPORT PROGRAM APPLY TO CHEESE

In the past we have reported on a number of problems with FDA's inspection program for imported foods. Because FDA's regulation procedures for all imported foods are the same, these concerns may also be relevant to imported cheese. For example, we have reported our concerns about FDA's low sampling rate for all imported foods--about 2 percent. Because FDA's sample selection is targeted to those products or importers with a history of violations, it may not be representative of all products entering the United States and may not provide adequate coverage of all imported products. Although FDA samples a higher percentage of imported cheese--about 3 percent--it continues to target known violators. We believe that this low sampling rate may not provide adequate coverage of imported cheese.

Although FDA believes that its targeted approach to sampling is efficient and effective, given its limited resources, it is also concerned that only a small portion of imports is physically inspected. FDA officials told us that they would like to increase the level of inspection for all FDA-regulated imported foods, including cheese. New York district officials told us that they would like to double their current inspection coverage of imported food products; however, to do so would require additional resources.

In addition to the low rates of sampling for imported products, we have identified other problems in the past, including FDA's lack of adequate legal authorities and its inability to deter the distribution of contaminated imports. According to FDA officials, additional resources and legal authorities to strengthen FDA's general import inspection program would also result in better regulation of imported cheese. For example, New York district officials said that FDA should have the authority to require the destruction of imports that are a known health hazard, such as contaminated cheese, or at a minimum have the authority to stamp each container "Refused entry into the United States." They believe that this kind of authority would provide better control over contaminated products and prevent them from entering the United States at some other time or place.

CONCLUSIONS

In closing, Mr. Chairman, we believe that certification programs, such as the one with France, are a good policy, because they allow FDA to supplement its own inspection efforts by encouraging foreign governments to ensure that products exported to the United States are safe. However, we are concerned that certification programs may become merely paper exercises if they are not actively monitored by FDA. Without formal monitoring of agreements, such as the French agreement, FDA cannot know what impact, if any, these programs are having on the safety of imported products.

Our report that you are releasing today recommends that FDA develop a formal monitoring program that will allow it to determine the effectiveness of the French certification program, as well as other certification programs, as appropriate.

Mr. Chairman, that concludes my prepared statement. I will be happy to respond to questions that you or Members of the Subcommittee might have.

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